510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER	Gyne Ideas, Ltd. West of Scotland Science Park Glasgow, U.K.
CONTACT PERSON	Louis J. Mazzarese (U.S. Agent for GyneIdeas, Ltd.)
DATE PREPARED	November 20, 2002
CLASSIFICATION	Polymeric Surgical Mesh
COMMON NAME	Urethral Sling
PROPRIETARY NAME	Gyne Ideas Minitape RP™
PREDICATE DEVICES	K974098 – Tension Free Vaginal Tape (TVT) System (Ethicon, Inc.) K010553 – Biosling (Injetx, Inc.) K020007 – SAFYRE Sling (Corniche, LLC) K020110 – Surgical Mesh (Boston Scientific) K020652 – T-Sling (Herniamesh USA, Inc.) K020705 – SiiS#1 Tissue Suspension System (T.A.G. Medical Products, Ltd.) K021263 - SPARC Sling System (American Medical Systems)
DEVICE DESCRIPTION	The device consists of a polypropylene sling with integral serrated anchoring arms. The sling has an overall length of 14cm. It is supplied with two metal needles to aid in surgical placement of the device. The device is supplied sterile.
INTENDED USE	To be used as a pubourethral sling for the treatment of female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
TESTING	The device has been subjected to in-vitro and in-vivo testing which demonstrate the ability of the device to adequately restrain urethral tissue under conditions in excess of those encountered during normal clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Louis J. Mazzarese
Gyne Ideas, Ltd.
150 Aran Hill Road
FAIRFIELD CT 06824-1712

SEP 28 2012

Re: K023898
Trade/Device Name: Gyne Ideas Minitape RP™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: April 4, 2003
Received: April 7, 2003

Dear Mr. Mazzarese:

This letter corrects our substantially equivalent letter of June 18, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023898

STATEMENT FOR INDICATIONS FOR USE

The subject device is intended to be used as a pubourethral sling for the treatment of female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023898